K132854

DEC 23 2013



# 510(k) Summary

1. **Type of Submission:** Traditional

2. **Submitter:**

| | |
|---|---|
| **Address:** | Yung Sheng Optical Co., Ltd.<br>3F-1, No.6, Jhongke Road, Daya District, Taichung City 42881<br>Taiwan |
| **Manufacturing facility:** | No.8, Keya 2nd Road, Daya District, Taichung City 42881,<br>Taiwan |
| **Phone:** | (04) 25658384 #156、191 |
| **Fax:** | (04) 25658387 |
| **Contact:** | Wen-Han Chen / Mavis Kao |
| **Date prepared:** | December 17th, 2013 |

3. **Identification of the Device**

| | |
|---|---|
| **Proprietary/Trade name:** | Eye Secret 38 UV Aspheric (polymacon) Soft<br>(hydrophilic) Contact Lens for Daily Wear |
| **Common Name:** | Contact Lens |
| **Classification Name:** | Lenses, Soft Contact, Daily Wear |
| **Device Classification:** | II |
| **Regulation Number:** | 886.5925 |
| **Panel:** | Ophthalmic |
| **Product Code:** | LPL for Lenses, Soft Contact, Daily Wear<br>MVN for Lens, Contact, (Disposable) |

4. **Identification of the Predicate Device**

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|---|---|
| **Predicate Device Name:** | BAUSCH & LOMB Soflens MultiFocal (polymacon) Visibility<br>Tinted Contact Lens |
| **Manufacturer:** | BAUSCH & LOMB |
| **510(k) Number or Clearance Information:** | K020927 |

## 5. Intended Use and Indications for Use of the subject device

The Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for the correction of ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

## 6. Device Description

The Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is manufactured by using cast molding method. The lens material, polymacon, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) crosslinked with ethylene glycol dimethacrylate (EGDMA). A UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range of 280 to 315 nm and less than 50% in the UVA range of 316 to 380 nm. The lenses are tinted blue for visibility purposes with the color additives, C.I. Reactive Blue No.4. The Lenses are available as aspheric lenses.

## 7. Summary of Clinical Study

Polymacon lenses have been used widely. Their safety and effectiveness have been well documented and cleared by FDA. BAUSCH & LOMB Soflens MultiFocal (polymacon) Visibility Tinted Contact Lens (K020927) submitted by BAUSCH & LOMB is an example.

Clinical study for Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is not required for the premarket notification as the USAN name and process are the same as the above mentioned predicate devices.

## 8. Non-clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear. The results of all testing demonstrated that the safety and effectiveness of the Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is equivalent to the

BAUSCH & LOMB Soflens MultiFocal (polymacon) Visibility Tinted Contact Lens (K020927). The following tests were conducted as recommended by the FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, February 27, 1997:

- Toxicity
  1. Acute Systemic Injection Study: The lens material meets the requirements of the systemic injection test and is considered non-toxic.
  2. White Rabbit Ocular Irritation Test: Ocular irritation test was performed and produced no ocular irritation.
  3. Cytotoxicity Test: The test article meets the requirements of ISO 10993-5.
- Extractables
- Finished Lens Parameters
- Light Transmittance
- Refractive Index
- Water Content
- pH and Osmolality
- Specific Gravity
- Physical Compatibility
- Oxygen permeability
- Mechanical Comparative Testing
- Shelf-life test

The results of the non-clinical testing demonstrated that the Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate device.

**9. <u>Substantial Equivalence Determination</u>**

The Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear submitted in this 510(k) file is substantially equivalent in intended use, technology/principles of operation, materials and performance to the cleared BAUSCH & LOMB Soflens MultiFocal (polymacon) Visibility Tinted Contact Lens which is the subject of K020927. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

| Item | Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear | Predicate Device (K020927) BAUSCH & LOMB Soflens MultiFocal (polymacon) Visibility Tinted Contact Lens |
|---|---|---|
| Regulatory Number | 886.5925 | 886.5925 |
| Classification | II | II |
| Intended Use | Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. | BAUSCH & LOMB Soflens MultiFocal (polymacon) Visibility Tinted Contact Lens is indicated for daily wear for the correction of the refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. |
| Prescription Use | Yes | Yes |
| **Material** | **polymacon** | **polymacon** |
| Manufacturing Method | Cast Molded | Cast Molded |
| Water Content | 38% | 38% |
| Powers | -0.50D ~ -12.00 D | ± 20.00D |
| Light Transmittance | 95% ± 5% | ≧ 96% |
| UV-A | < 50% | - |
| UV-B | < 5% | - |
| Refractive Index | 1.440 ± 0.005 | 1.4375 |
| Base Curve | 8.6 ± 0.2mm | 7.5mm ~ 9.5mm |
| Diameter | 14.0 ± 0.2mm | 13.5mm ~ 15.5mm |
| Tint | C.I. Reactive Blue #4 | Reactive Blue Dye 246 |

## 10. Conclusion

After analyzing bench tests, safety testing data, it can be concluded that Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

Mr. Yu-Ming Hsieh
Factory Director
3F-1, No. 6, Jhongke Road
Daya District Taichung City 42881
Taiwan

Re: K132854/S001
Trade Name: Eye Secret 38 UV (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: II
Product Code: LPL
Dated: November 22, 2013
Received: December 2, 2013

Dear Mr. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K132854

Device Name: Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joseph C. Hutfles -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K132854